

# Neuromodulation Device

## STIMPOD™

NMS460



**XAVANT**  
TECHNOLOGY

PRODUCT CODE: XT-46006-EN

XM400-31A04-02

## Manufacturer

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## Indications for use:

The NMS460 is a Transcutaneous Electrical Nerve Stimulation device used for symptomatic relief and management of chronic intractable pain and/or as an adjunctive treatment in the management of post-surgical pain, post traumatic acute pain problems, as well as an adjunct for pain control due to rehabilitation.

## Contraindications:

Use of the NMS460 can affect the operation of demand-type cardiac pacemakers. The NMS460 is not recommended for patients with known heart disease without a physician's evaluation of risk. Do not stimulate over the eyes or carotid sinus nerves. Do not apply the NMS 460 for:

- undiagnosed pain syndromes until etiology is established,
- electrode placement that causes current to flow transcranially (through the head).

## Warnings:

- Read the entire User Manual before attempting to use the device.
- Use of cables or accessories other than those supplied with the NMS460 may result in serious injury.
- Maintenance on this device may only be performed by the manufacturer or persons explicitly authorized by the manufacturer.
- Do not use the NMS460 in close proximity to equipment that produces strong electromagnetic fields, such as high frequency surgical equipment. The cable leads could act as antennae and dangerous currents could be induced as a result.

## Cautions:

- Remove elements which may adversely affect the connection between the ECG electrodes and the skin, e.g., dirt, hair, oil.
- Ensure that ECG electrodes are not damaged or dried out.
- ECG electrodes may be used in the higher current ranges (> 10 mA).
- This product must be stored at room temperature.
- This product must be transported in the carry case provided.
- This product and all the accessories have been certified latex free.

## Warranty:

- The NMS460 carries a 12 Month Warranty against defects, provided that the device was used in accordance with the operating instructions.
- The NMS460 enclosure should not be opened under any circumstances. Opening the unit will void the warranty.

## STIMPOD 460 conforms to the following standards:

- IEC 60601-1, IEC 60601-2-10
- IEC 60601-1-2: CISPR 11 Group1 class B; IEC 61000-4-2; IEC 61000-4-3
- ISO 13485, Directive 93-42-EEC

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# 1) Getting to know the STIMPOD

## 1.1) Device Description

The STIMPOD NMS460 is a Low Frequency Neuromodulation Transcutaneous Electrical Nerve Stimulation device, used for symptomatic relief and management of chronic intractable pain and/or as an adjunctive treatment in the management of post-surgical pain, post-traumatic acute pain, as well as an adjunct for pain control due to rehabilitation.

The STIMPOD NMS460 offers two types of waveforms for the treatment of pain. The first is a Monophasic Square Wave, which is typical of normal TENS machines. The second waveform is a Hybrid RF waveform which consists of a Monophasic Square Wave with a superimposed Radio Frequency waveform. This waveform is proprietary and is unique to the NMS460. For more information on the benefits of using this modality please visit [www.xavant.com](http://www.xavant.com).

## 1.2) Accessories

**WARNING:** Use of cables or other accessories other than those supplied with the STIMPOD NMS460 may result in serious injury.

**NOTE:** ECG Electrodes are not included in this package.



Carry Case



### Probe Cable:

- The red (anode) connector is designed to clip on to a standard ECG electrode.
- The ergonomically designed Probe is used to stimulate the affected area.

### Batteries:

- This unit uses 4 x AAA penlight batteries.
- Alkaline batteries are recommended.
- When the battery is depleted the unit will prompt the user to replace the battery and switch off.
- Switch device off before replacing battery.
- Remove battery if the device is not to be used for an extended period of time, to prevent leakage.

**WARNING:** If battery acid has leaked into the device essential circuitry may have been compromised. In the event of leakage the device must be returned to its manufacturer for safety checks and possible repairs.



### 1.3) Device Layout

#### Cable Connector

- Insert the Cable

#### Enter / Frequency Button

- Press to toggle between Stimulating Frequencies.
- Press to Enter in setup menu.

#### Stimulating LED indicator

- Flashing Green: Stimulus delivered.
- Flashing Red: Open Circuit detected.

#### Menu / Pulse Width Button

- Press to toggle between Pulse Widths.
- Press and hold to access Setup Menu.

#### Pause Button

- Press to Start /Stop Stimulation.

#### The Wheel

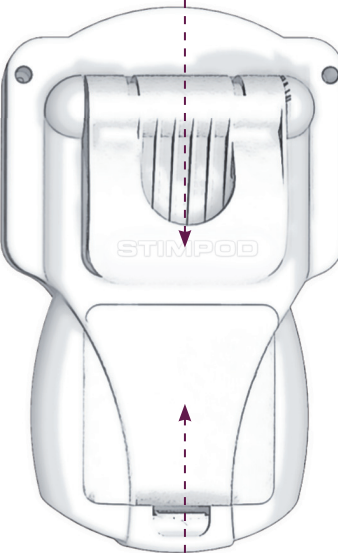
- Adjust current in the main operating mode.
- Navigate the Setup Menus.

#### On / Off Button

- Press to switch unit on / off.

Display

Multi Functional Clip



Battery Compartment Cover

## 1.4) Screen Layout

- Countdown timer

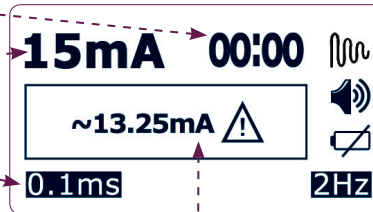
- Current Setting

Adjust using Wheel.

- Pulse Width Setting

Adjust using Menu / Pulse Width button.

- Information Screen



- Indicators

Square Wave Hybrid RF

Speaker Volume

Battery Status

- Stimulating Frequency Setting

Adjust using Enter / Hz button.

### Actual current delivered

The current displayed in this screen is the actual Average Current delivered to the patient. If there is a discrepancy of more than 10% between this measured current and the current setting a warning sign "⚠" will appear. If the actual current delivered is not the same as the current setting it means that the impedance of the circuit between the device and patient is too high (higher than 13 kOhm). This is most likely caused by a poor grounding electrode/skin connection.

~13,25mA ⚠

INSERT CABLE ⚠

### Insert Cable:

This is the first prompt which the user will encounter as the unit is switched on, and signals that the unit is waiting for the cable to be inserted.

PAUSE ⚠

### Pause:

This warning informs the user that the PAUSE button was pressed. The STIMPOD NMS460 will pause all its activities and wait for the PAUSE button to be pressed again.

CABLE NOT  
RECOGNISED ⚠

### Cable not recognised:

This warning informs the user that the inserted cable is not compatible with the STIMPOD NMS460.

REPLACE  
BATTERIES ⚠

### Replace Batteries:

This warning informs the user that the batteries are depleted beyond an acceptable level. Continuing to operate the device thus will make it unreliable. To prevent this the STIMPOD NMS460 flashes this warning for 4 seconds before switching off.

OPEN CIRCUIT  
DETECTED ⚠

### Open Circuit Detected:

This warning informs the user that the two electrodes (i.e. Ecg electrode and treatment probe) do not form the closed circuit. This warning will be accompanied by a red flashing LED, every time the unit attempts to stimulate.

⚠ ⚠ ⚠

### Error:

The STIMPOD NMS460 has detected a component failure. Please send the device back to the manufacturer for repair!

## 1.5) Adjusting Settings

### Adjusting the Current

Current Range: 0 – 30 mA adjustable in 1mA increments

Circle the Wheel to adjust the current

### Adjusting the Pulse Width

Options in the Setup Menu: 0.1ms, 0.2ms

Default: 0.1ms

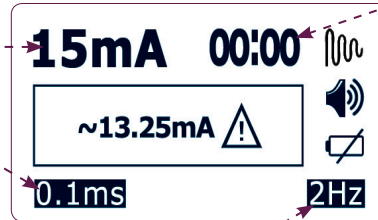
Press **Menu/Pulse** Width button to toggle between different Pulse Widths.

### Adjusting the Stimulation Frequency

Options in the Setup Menu: 1Hz, 2Hz, 5Hz, 10 Hz

Default: 2Hz

Press **Enter/Hz** button to toggle between different stimulating frequencies.



## 1.7) Countdown Timer

- Start the stimulation by pressing the play/pause button.
- The device will automatically start stimulation at the set frequency and the countdown timer will start.
- The countdown will start from the time set in the "Countdown Timer" option in the main menu.
- Pause the timer and the stimulation by pressing the play/pause button.
- Reset the timer by pressing and holding the play/pause button for longer than 2 seconds.
- The Countdown Timer defaults at 10 minutes. This setting can be changed in the Setup Menu.
- The Stimulation will stop when the timer reaches 00:00. An alarm will sound and the Countdown Timer will reset.

## 1.6) Open Circuit Detection

A few milliseconds prior to the actual stimulation, an impedance measurement is made to detect whether the connection between the STIMPOD NMS460 and the patient comprises a closed circuit.

### Closed Circuit Detected:

- Stimulation will take place.
- Stimulating sound will be heard
- The LED stimulus indicator will pulse **green** with every successful stimulus attempt.
- The **information screen** will show the value of the actual current delivered.

### Open Circuit Detected:

- No stimulation will take place.
- No stimulating sound will be heard.
- The LED stimulus indicator will pulse **red** with every unsuccessful stimulus attempt.
- A **warning screen** will appear in the diagnostics screen indicating that an open circuit was detected.

**OPEN CIRCUIT  
DETECTED**

## 1.8) Shutdown

### Auto Shutdown

STIMPOD NMS460 will automatically switch off after 10 minutes of no user or patient interaction.

### Battery Depleted

When the battery is depleted the unit will prompt the user to replace the battery and switch off.

## 1.9) Symbols on device battery clip



Manufacturer



Attention! See Instructions for Use



Separate collection for electrical and electronic equipment (Applicable to EU community only)



Manufacturing Date (Year)



Serial Number



Representative in the EU

## 2) Setting up Device Defaults

Access the **Setup Menu** by pressing and holding the **Menu/Pulse Width Button**. The setup menu allows the user to customise all the default settings.

### 2.1) Languages

DEFAULT: English

Use the **Wheel** to navigate to **LANGUAGE**. Press **enter** to select.

LANGUAGE
<input checked="" type="radio"/> ENGLISH
<input type="radio"/> FRANCAIS
<input type="radio"/> ITALIANO
<input type="radio"/> NEDERLANDS
<input type="radio"/> ESPAÑOL

To select another default language, use the Wheel to navigate to the preferred language. Press **enter** to select. The radio button next to the selected language will show that it is activated. To exit scroll down the menu to **EXIT MENU** and press **enter**.

LANGUAGE
YOU HAVE SELECTED: ENGLISH
ACCEPT: <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO

A conformation screen will show your selection, with an option to **ACCEPT**.

**YES** will take you back to the main **Setup Menu**.  
**NO** will take you to the previous screen.

### 2.2) Stimulation Mode

DEFAULT: Hybrid RF

Options: Hybrid RF, Square Wave

Use the **Wheel** to navigate to **STIMULATION MODE**. Press **enter** to select.

SETUP MENU
1 LANGUAGE
2 STIMULATION MODE
3 PULSE WIDTH
4 FREQUENCY
5 COUNTDOWN TIMER
6 SPEAKER VOLUME
7 BACKLIGHT
8 USER INFORMATION
EXIT

#### Hybrid RF Mode

The "📶" indicator in the main window tells the user that the device is in Hybrid RF Mode.

STIMULATION MODE
<input checked="" type="radio"/> HYBRID RF
<input type="radio"/> SQUARE WAVE
EXIT MENU

The **radio button** next to **Hybrid RF Mode** will show that it is **activated**.

To exit scroll down the menu to **EXIT MENU** and press **enter**.

STIMULATION MODE
YOU HAVE SELECTED: HYBRID RF MODE
ACCEPT: <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO

A conformation screen will show your selection, with an option to **ACCEPT**.

**YES** will take you back to the main **Setup Menu**.  
**NO** will take you to the previous screen.

#### Square Wave Mode

The "📶" indicator in the main window tells the user that the device is in Square Wave Mode.

STIMULATION MODE
<input type="radio"/> HYBRID RF
<input checked="" type="radio"/> SQUARE WAVE
EXIT MENU

The **radio button** next to **Square Wave Mode** will show that it is **activated**.

To exit scroll down the menu to **EXIT MENU** and press **enter**.

STIMULATION MODE
YOU HAVE SELECTED: SQUARE WAVE MODE
ACCEPT: <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO

A conformation screen will show your selection, with an option to **ACCEPT**.

**YES** will take you back to the main **Setup Menu**.  
**NO** will take you to the previous screen.



## 2.3) Pulse Width Options

DEFAULT: 0.1ms

Options: 0.1ms, 0.2ms

Use this setup function to activate the preferred pulse widths.

Use the **Wheel** to navigate to **PULSE WIDTH** in the main menu. Press **enter** to select.

**PULSE WIDTH**

☒ 0.1 ms  
☐ 0.2 ms

**EXIT MENU**

Within the **PULSE WIDTH** Menu, the radio button next to the selected pulse width will show that they have been activated.

**PULSE WIDTH**

**YOU HAVE SELECTED:**  
0.1 ms    0.2 ms

**ACCEPT:** ☒ YES    ☐ NO

To exit scroll down the menu to **EXIT MENU** and press **enter**. A confirmation screen will show your selection, with an option to **ACCEPT**.

**YES** will take you back to the main **Setup Menu**.

**NO** will take you back to the previous screen.

NOTE: If all pulse widths are deselected the STIMPOD NMS460 will default to 0.1ms and 0.2ms.

## 2.4) Stimulating Frequency

DEFAULT: 2Hz

Options: 1Hz, 2Hz, 5Hz and 10 Hz

Use the **Wheel** to navigate to **FREQUENCY** in the main menu. Press **enter** to select.

**FREQUENCY**

☒ 1 Hz  
☐ 2 Hz  
☐ 5 Hz  
☐ 10 Hz

**EXIT MENU**

Within the **FREQUENCY** Menu, the radio button next to the selected frequency will show that it has been activated. Scroll down the menu to **EXIT MENU** and press **enter**.

**FREQUENCY**

**YOU HAVE SELECTED:**  
1 Hz

**ACCEPT:** ☒ YES    ☐ NO

A confirmation screen will show your selection with an option to **ACCEPT**.

**YES** will take you back to the main **Setup Menu**.

**NO** will take you back to the previous screen.

## 2.5) Countdown Timer

DEFAULT: 10 minutes

Options: Adjustable from 00:01 to 59.59

Use the **Wheel** to navigate to the **COUNTDOWN TIMER**. Press **enter** to select.

This timer counts down the desired treatment time.

'**Minutes**' will be highlighted: Use the **Wheel** to adjust the settings. Press **enter** to accept the desired setting.

'**Seconds**' will be highlighted: Use the **Wheel** to adjust the settings. Press **enter** to accept the desired setting.

A confirmation screen will show your updated values with an option to **ACCEPT**.

**YES** will take you back to the main **Setup Menu**.

**NO** will take you back to the previous screen.

**COUNTDOWN TIMER**

**ADJUST RANGE:**  
**MINUTES:** 01  
**SECONDS:** 20

**COUNTDOWN TIMER**

**YOU HAVE SELECTED:**  
01:20

**ACCEPT:** ☒ YES    ☐ NO

## 2.6) Speaker Volume

DEFAULT: Medium

Options: Off – [X]    Low – [1]    Medium – [2]    High – [3]

Use the **Wheel** to navigate to **SPEAKER VOLUME**. Press **enter** to select.

**SPEAKER VOLUME**

☐ OFF  
☐ LOW  
☒ MEDIUM  
☐ HIGH

**EXIT MENU**

Use the wheel to select the appropriate volume and **enter**. Scroll down the menu to **EXIT MENU** and press **enter**.

**SPEAKER VOLUME**

**YOU HAVE SELECTED:**  
HIGH

**ACCEPT:** ☒ YES    ☐ NO

A Confirmation screen will show the new selected volume with an option to **ACCEPT**.

**YES** will take you back to the main **Setup Menu**.

**NO** will take you back to the previous screen.

## 2.7) Backlight

DEFAULT: 5 Seconds

Options: OFF, 5 seconds, 60 seconds, and Always On

Use the **Wheel** to navigate to **BACKLIGHT** in the main menu. Press **enter** to select.

**BACKLIGHT**

☐ OFF  
☐ 5 sec  
☐ 60 sec  
☒ ALWAYS ON

**EXIT MENU**

Within the **BACKLIGHT** Menu, the radio button next to the selected setting will show that it has been activated.

Scroll down the menu to **EXIT MENU** and press **enter**.

A confirmation screen will show your selection, with an option to **ACCEPT**.

**YES** will take you back to the main **Setup Menu**.  
**NO** will take you back to the previous screen.

**NOTE:** If the selected backlight option is 'Always On' the battery life will be drastically shortened.

**BACKLIGHT**

**YOU HAVE SELECTED:  
ALWAYS ON**  
**⚠ BATTERY LIFE WILL BE  
ADVERSELY AFFECTED**

**ACCEPT: YES NO**

## 2.8) User Information

DEFAULT: No default

The STIMPOD NMS460 offers the user the option to enter user information. Two lines of **20 characters** each may be entered. This user information will be displayed for two seconds when unit is switched on, as per example.

Use the **Wheel** to navigate to **USER INFORMATION** in the main menu. Press **enter** to select.

**USER INFORMATION**

**ENTER TEXT LINE 1**  
DR X

**⚠ CHARACTERS LEFT: 16**

A cursor will appear at the first character's position. Use the **Wheel** to **navigate to different characters**. Press **enter** to select the character and move to the next space.

Press enter on the '**←**' character for backspace, on the '' character for a space and on the '**↩**' character to enter the line. A warning underneath the textbox will show the available characters in the line.

**USER INFORMATION**

**YOU HAVE ENTERED:**  
DR X

**ACCEPT: YES NO**

When both lines have been entered, a confirmation screen will show your selection, with an option to **ACCEPT**.

**YES** will take you back to the main **Setup Menu**.

**NO** will take you back to the first **USER INFORMATION** screen.

# 3) Technical Notes

## 3.1) Specifications

Current Range:	0 - 30mA ± 5%
Pulse Width Options:	0.1ms, 0.2ms
Maximum Stimulation Voltage:	220V
Waveform:	Monophasic square wave/ HYBRID RF wave
Stimulating Frequency:	1Hz , 2Hz, 5Hz, 10Hz ± 5%
Load Impedance:	0 kOhm - 7 kOhm
Device Classification:	Class IIa, Type BF
Power Supply:	4 x AAA alkaline batteries
Power Consumption:	17mA
Weight:	130g
Dimensions:	145mm x 90mm x 30mm
Operating Temperature:	10 - 40 ° Celsius
Storage and Transport Temperature:	0 - 50 ° Celsius
Operating Humidity:	90% Relative Humidity

## 3.2) Cleaning and Disinfecting STIMPOD NMS460

**Cleaning:** Soap and water, applied with a damp cloth is suitable to clean and disinfect the STIMPOD NMS460. It is imperative that no moisture penetrates the STIMPOD.

**Disinfecting:** Any commercially available methanol - free disinfectant in an ethyl alcohol base can be used for disinfection.





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